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EXAMINER

SOUAYA, JEHANNE E

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/657,279

Applicant(s)  
Xu et al.

Examiner  
Jehanne Souaya

Art Unit  
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 3-6, and 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Sep 6, 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4,7,8
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Please note that the art unit designation for the examiner has changed from 1655 to 1634.

#### ***Election/Restriction***

1. Applicant's election without traverse of Group II, claims 2 and 7, SEQ ID NO 108, in Paper No. 10 is acknowledged. Claims 1, 3-6, and 8-17 have been withdrawn from consideration as being drawn to non elected subject matter. An action on the merits of claims 2 and 7 follows. Please note, with regard to claim 1, as claim 2 is dependent on polynucleotide sequences of claim 1, claim 1 will be considered for purposes of 35 USC 112/first and second paragraph rejections as they apply to claim 2. Applicants should amend claim 2, however, to incorporate the appropriate subject matter of claim 1 and to reflect the election of the specific sequence of SEQ ID NO 108.

#### ***Priority***

2. Applicant's claim for priority under 35 USC 120 and 35 USC 365© is acknowledged. The claims have been awarded the benefit of the filing date of 2/9/1998 as the subject matter in claims 2 and 7 of the present application (SEQ ID NO 108) was disclosed in application 09/020,956 filed 2/9/1998. With regard to applicant's claim for priority to applications 08/904,804 filed 8/1/1997, and 09/806,099 filed 2/25/1997, the claims have not been awarded the benefit of either filing date as the subject matter disclosed in the present claims was not taught in either the '956 or the '804 applications.

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***Drawings***

3. New corrected drawings are required in this application because some of the drawings are faded copies and the details of the drawings, such as nucleic acid sequences, polypeptide sequences and figure legends cannot be discerned. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. Upon examination of the application, the examiner could not find evidence that applicants submitted the drawings as informal. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

***Enablement***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence of SEQ ID NO 108, a fusion protein comprising a polypeptide comprising the amino acid sequence of SEQ ID NO 108, an isolated polypeptide encoded by the nucleic acid sequence of SEQ ID NO 107, and a fusion protein comprising a polypeptide encoded by the nucleic acid sequence of SEQ ID NO 107, does not reasonably provide enablement for an isolated

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polypeptide comprising: 1) an amino acid sequence "recited in" SEQ ID NO 108, 2) sequences having at least 70% or 90% identity to a sequence of SEQ ID NO 108, 3) a sequence encoded by a sequence provided in SEQ ID NO 107, 4) a sequence encoded by a complement of the sequence "provided in" SEQ ID NO 107, 5) a sequence encoded by a sequence consisting of at least 20 contiguous residues of a sequence "provided in" SEQ ID NO 107, 6) a sequence that hybridizes under moderately stringent conditions to a sequence "provided in" SEQ ID NO 107, 7) a sequence encoded by a sequence having at least 75% or 90% identity to a sequence of SEQ ID NO 107, 8) degenerate variants of a sequence "provided in" SEQ ID NO 107, or sequence having at least 70% or 90% identity to a sequence encoded by a sequence of 3-7 above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to mutants, variants and homologs of the polypeptide of SEQ ID NO 108 as well as fragments of the polypeptide of SEQ ID NO 108, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 was over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 125, line 16-page 126 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out of 5 prostate carcinoma samples tested, and that the staining pattern of anti-P504S antibodies

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(P504S is the polypeptide of SEQ ID NO 108) in benign prostate cells was a light nuclear staining while that of prostate carcinoma samples was a cytoplasmic granular staining. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. The specification, however, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), however the specification does not teach the function of any of these splice variants, nor whether they were over expressed in prostate tumor samples vs normal prostate tissue.

Polypeptides encompassed by the claims, such as: an isolated polypeptide comprising: 1) an amino acid sequence "recited in" SEQ ID NO 108, 2) sequences having at least 70% or 90% identity to a sequence of SEQ ID NO 108, 3) a sequence encoded by a sequence provided in SEQ ID NO 107, 4) a sequence encoded by a complement of the sequence "provided in" SEQ ID NO 107, 5) a sequence encoded by a sequence consisting of at least 20 contiguous residues of a sequence "provided in" SEQ ID NO 107, 6) a sequence that hybridizes under moderately stringent conditions to a sequence "provided in" SEQ ID NO 107, 7) a sequence encoded by a sequence having at least 75% or 90% identity to a sequence of SEQ ID NO 107, 8) degenerate variants of a sequence "provided in" SEQ ID NO 107, or sequence having at least 70% or 90% identity to a sequence encoded by a sequence of 3-7 above; include a large number of mutants, variants, and homologs of SEQ ID NOS 107 and 108, resulting from missense, frameshift and

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truncation mutations, from any source, which have not been taught in either the specification or the art. With regard to sequences “recited in” SEQ ID NO 108 or sequences “provided in” SEQ ID NO 107, since the specification does not make clear the scope of such language, the claims have been interpreted to encompass a polypeptide that can have as little as 1 amino acid or nucleotide sequence in common with either SEQ ID NO 108 or 107 respectively, as well as an unlimited number of sequences on either side. With regard to a sequence encoded by “a complement” of the sequence “provided in” SEQ ID NO 107, it is unclear whether the claim intends a sequence that is complementary to SEQ ID NO 107, which encompasses a single nucleotide, or “the full complement” of SEQ ID NO 107. Therefore, the claim has been broadly interpreted to encompass the former. With regard to a sequence consisting of at least 20 contiguous residues of a sequence provided in SEQ ID NO 107, the claims have been interpreted to encompass a polypeptide encoded by any sequence that can have as little as 20 contiguous nucleotides identical to SEQ ID NO 107. The specification, however, has not taught the activity or sequence of any of the large number of polypeptides encompassed by the broadly claimed invention. With regard to a polypeptide encoded by a sequence that hybridizes under moderately stringent conditions to SEQ ID NO 107, a polypeptide encoded by a sequence that has 75% or 90% identity to a sequence of SEQ ID NO 107, or to a polypeptide that has 70% or 90% identity to a sequence of SEQ ID NO 108, the sequences encompass mutants, variants and homologs from any source with either retained or altered biological activity. It is further noted that because the claim does not make clear whether the % identity is to the full length sequence or a portion of

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the sequence, the claim has been interpreted to encompass sequences with a specific % identity to a portion of the sequence. Since the specification does not teach the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the skilled artisan would not be able to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity and it would further be unpredictable as to how the skilled artisan could modify the molecule without altering its biological activity.

A sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal  $\alpha$ -methylacyl-CoA racemase which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while the specification, does not teach or suggest the use of the claimed polypeptides with adult onset sensory motor neuropathy, does not teach the function or biological activity of the polypeptide of SEQ ID NO 108 and specifically teaches that no significant homologies were found with SEQ ID NO 107 and the EMBL and GenBank databases (p. 120, lines 15-16). Therefore, based on the lack of guidance from the specification or the art, the skilled artisan would not be able to determine a predictable correlation between variants, mutants, or homologs of the polypeptide of SEQ ID NO 108 and an association to prostate cancer.

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A correlation between mutants, variant and homologs encompassed by the claims and a specific biological activity and its association to prostate cancer is clearly unpredictable in light of the lack of guidance from the specification and the state of the art with regard to the specific biological function of the polypeptide encoded by SEQ ID NO:108. Since the specification does not teach the specific biological function or activity of the polypeptide of SEQ ID NO 108, and neither the specification nor the art teach how the function of the polypeptide is associated to prostate cancer nor how the skilled artisan could modify the polypeptide of SEQ ID NO 108 to obtain a polypeptide with either retained or modified function in association with its differential expression in prostate cancer, the skilled artisan would be required to perform undue experimentation to make or use the biologically active or altered polypeptides encompassed by the broadly claimed invention. To practice the invention as broadly as it is claimed, the skilled artisan would first have to determine the function of the polypeptide of SEQ ID NO 108 and its association to prostate cancer. The skilled artisan would then have to determine what amino acid residues were associated with the expression of the polypeptide in relation to prostate cancer, and then would have to determine which amino acids could be modified to either retain biological function or to result in a protein with altered function. Given that the art teaches that a single amino acid change can alter the function of a biomolecule (see Proudfoot et al, Journal of Biological Chemistry, vol. 271, pp 2599-2603, which teaches that extension of recombinant human RANTES by a single residue [Met-RANTES] at the amino terminus was sufficient to produce a potent and selective antagonist - see abstract) and that some of these changes are

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unpredictable, and given that the specification does not teach the function of the polypeptide of SEQ ID NO 108 and its association to prostate cancer such analyses would require trial and error, thus constituting undue experimentation. It is noted that because the skilled artisan would be required to perform undue experimentation to make and use the polypeptides of claim 2, undue experimentation would also be required to make or use fusion proteins comprising the polypeptide of claim 2.

***Written Description***

6. Claims 2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to mutants, variants and homologs of the polypeptide of SEQ ID NO 108 as well as fragments of the polypeptide of SEQ ID NO 108, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 was over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 125, line 16-page 126 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out of 5 prostate carcinoma samples tested, and that the staining pattern of anti-P504S antibodies

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(P504S is the polypeptide of SEQ ID NO 108) in benign prostate cells was a light nuclear staining while that of prostate carcinoma samples was a cytoplasmic granular staining. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. The specification, however, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), however the specification does not teach the function of any of these splice variants, nor whether they were over expressed in prostate tumor samples vs normal prostate tissue.

With regard to sequences “recited in” SEQ ID NO 108 or sequences “provided in” SEQ ID NO 107, since the specification does not make clear the scope of such language, the claims have been interpreted to encompass a polypeptide that can have as little as 1 amino acid or nucleotide sequence in common with either SEQ ID NO 108 or 107 respectively, as well as an unlimited number of sequences on either side. With regard to a sequence encoded by “a complement” of the sequence “provided in” SEQ ID NO 107, it is unclear whether the claim intends a sequence that is complementary to SEQ ID NO 107, which encompasses a single nucleotide, or “the full complement” of SEQ ID NO 107. Therefore, the claim has been broadly interpreted to encompass the former. With regard to a sequence consisting of at least 20 contiguous residues of a sequence provided in SEQ ID NO 107, the claims have been interpreted to encompass a polypeptide encoded by any sequence that can have as little as 20 contiguous

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nucleotides identical to SEQ ID NO 107. The specification, however, has not taught or described the activity or sequence of any of the large number of polypeptides encompassed by the broadly claimed invention. With regard to a polypeptide encoded by a sequence that hybridizes under moderately stringent conditions to SEQ ID NO 107, a polypeptide encoded by a sequence that has 75% or 90% identity to a sequence of SEQ ID NO 107, or to a polypeptide that has 70% or 90% identity to a sequence of SEQ ID NO 108, the sequences encompass mutants, variants and homologs from any source with either retained or altered biological activity. It is further noted that because the claim does not make clear whether the % identity is to the full length sequence or a portion of the sequence, the claim has been interpreted to encompass sequences with a specific % identity to a portion of the sequence. Since the specification does not teach or describe the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the skilled artisan would not be able to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity. Since the specification does not teach or describe the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the disclosed structural feature of SEQ ID NO 108 does represent a substantial portion of the claimed genus of polypeptides.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a polypeptide encoded by the polynucleotide of SEQ ID NO 107 and the polypeptide of SEQ ID NO 108, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Applicant should note that because the polypeptide of claim 2 does not meet the written description requirement, a fusion protein comprising the polypeptide of claim 2 also lack written

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description. Accordingly, the specification does not provide a written description of the invention of claims 2 or 7.

*Indefinite*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 2, in section a is indefinite in the recitation of “recited in” as it is unclear if the term is meant to encompass a polypeptide comprising the sequence “consisting” of SEQ ID NO 108, or a polypeptide that comprises a sequence “within” SEQ ID NO 108. The specification does not define the meaning of this term, and therefore, the metes and bounds of the claim are unclear.

B) Claim 2, in sections b and c, is indefinite in the recitation of % identity as it is unclear if the claim encompasses polypeptides that have the disclosed % identity to a portion of the polypeptide of SEQ ID NO 108 or the full length of the polypeptide of SEQ ID NO 108. (The same analysis holds for claim 1, sections e and f).

C) Claim 2, section d is indefinite as it is drawn to a polypeptide encoded by a sequence provided in SEQ ID NO 107 or the complement of a sequence provided in SEQ ID NO 107 or to degenerate variants of a sequence provided in SEQ ID NO 107. The recitation of “provided in”

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is unclear as it cannot be determined if the recitation is meant to encompass the sequence “consisting” of SEQ ID NO 107 or a sequence “within” SEQ ID NO 107. The specification does not define the meaning of the term and therefore, the metes and bounds of the claim are unclear.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 2 is rejected under 35 U.S.C. 102(a) as being anticipated by Accession number AAB72146.

AAB72146 teaches the polypeptide sequence of alpha-methylacyl-CoA racemase from mouse. The polypeptide of AAB72146 has about 73% sequence identity to the full length polypeptide of SEQ ID NO 108 (102 amino acid changes which includes the 21 amino acids at the C terminal end of SEQ ID NO 108 which are missing from AAB72146). Therefore, AAB72146 anticipates section b of claim 2. AAB72146 also anticipates section a and c of claim 2, because in section a, the claim is drawn to sequences “recited in” SEQ ID NO 108, and section c does not specify that the % identity is over the “full length” of the polypeptide. Amino acid

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residues 22-29 of SEQ ID NO 108 are identical to amino acid residues 1-8 of AAB72146, thus the claim, in sections a, b, and c is anticipated by AAB72146.

11. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Haldenwang (WO 93/03156, 2/18/1993).

Haldenwang teaches a polypeptide of 29 amino acids (Fig 1), of which, residues 19-25 are identical to amino acids 248-254 of SEQ ID NO 108. Therefore, Haldenwang anticipates claim 2, sections a-c because, in section a, the claim is drawn to sequences "recited in" SEQ ID NO 108, and sections b and c do not specify that the % identity is over the "full length" of the polypeptide. The polypeptide taught by Haldenwang is a polypeptide that comprises a sequence "recited in" SEQ ID NO 108, and has at least 70% and 90% identity to a sequence of SEQ ID NO 108.

12. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by JP06038763 (2/14/1994- accession number AAR49827 is being included).

JP06038763 teaches a polypeptide of 394 amino acids. Residues 126-134 are encoded by nucleotides 362-388 of SEQ ID NO 107. Therefore, JP06038763 anticipates claim 2 in section d as the polypeptide of JP06038763 comprises a sequence encoded by at least 20 contiguous residues of a sequence provided in SEQ ID NO 107 (section c of claim 1).

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### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application Nos. 09/568,100, 09/636,215, 09/593,793, and 09/605,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2 of the '100, '215, '793, and '783 applications recites in the alternative "an isolated polypeptide which comprises an amino acid sequence that is encoded by a polynucleotide sequence recited in SEQ ID NO 107". Claim 2, section a of the instant application is drawn to a polypeptide comprising an amino acid sequence recited in SEQ ID NO 108. It is noted that SEQ ID NO 107 encodes the polypeptide of SEQ ID NO 108, and that SEQ ID NO 107 of the instant application is identical to SEQ ID NO 107 of the '100, '215, '793, and '783 applications, therefore, claim 2 of the instant application and claim 2 of the '100, '215, '793, and '783 applications are coextensive in scope.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Conclusion*

15. No claims are allowable.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jehanne Souaya*

Jehanne Souaya  
Patent examiner  
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*4/19/2002*